



September 7, 2021

**VIA E-FILING**

The Honorable Leonard P. Stark  
J. Caleb Boggs Federal Building  
844 N. King Street  
Wilmington, DE 19801-3556

**RE: *Natera, Inc. v. ArcherDX, Inc., et al.***  
**C.A. No. 20-cv-125-LPS**

Dear Judge Stark:

Defendants ArcherDX, Inc. and Invitae Corp. (collectively “Defendants”) oppose Natera’s motion to amend its complaint to assert newly corrected claims of U.S. Patent No. 10,590,482 (“the 482 patent”). These claims include significantly altered language relative to the language that Natera has been asserting throughout the case.

Factors that may justify denying a motion to amend include undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, and undue prejudice to the opposing party by virtue of the allowance of the amendment. *See, e.g. Foman v. Davis*, 371 U.S. 178, 182 (1962). As documented below, such considerations weigh overwhelmingly against permitting Natera to file an amended complaint at this late stage. Indeed, before Natera even filed its motion to amend, Defendants had moved to strike Natera’s attempt to assert its newly corrected claims. In its motion to amend, Natera does not even attempt to address any of the points raised by Defendants in their motion to strike.

**I. Factual Background**

For the Court’s convenience, Defendants restate the factual background relevant to the instant dispute as originally laid out in their co-pending motion to strike.

The Patent Office conditioned issuance of the ’482 patent on inclusion of the limitation **“wherein (i) the adaptors each comprise a molecular barcode and/or (ii) at least one of the primers comprises a sequencing tag.”** D.I. 302, Ex. A at 2. Natera, however, never submitted proper paperwork to reflect the required language, and the ’482 Patent issued without this language. *See* D.I. 17, Ex. 3. After failing to correct the error, in April 2020, Natera asserted the uncorrected claims against Defendants in its Complaint. *See id.* Subsequently, Natera’s initial infringement contentions asserted solely the uncorrected claims. *See* D.I. 302, Ex. B. In their First Amended Invalidity Contentions, Defendants identified Natera’s omission of the requisite claim language and explained that this rendered the claims invalid. *See* D.I. 302, Ex. C at 63. Almost two months later, and 15 months after the patent issued, Natera for the first time requested that the Patent Office correct the ’482 patent claims. *See* D.I. 302, Ex. D. Natera never notified Defendants of this request.

Nevertheless, in its final infringement contentions dated July 12, 2021, Natera purported to assert for the first time the newly corrected claims. *See* D.I. 302, Ex. F at 41–54. The Patent

Office, however, did not even issue a certificate of correction until seven days later, on July 19, 2021. *See* D.I. 302, Ex. E; Ex. 1. Notably, Natera failed to state that it had changed the claim language in its contentions to new language for which the Patent Office had not yet even issued certificate of correction. Thus, Natera asserted *sub silentio* claims that it had no right to assert, ostensibly in the hopes that nobody would notice. At no point up until a few days ago did Natera seek to amend its complaint to remove the uncorrected, invalid claims of the '482 Patent, and add the corrected claims.

## II. Natera Was Not Diligent In Seeking To Amend

Natera cannot credibly contend that it was diligent in seeking to amend.

While Natera asserts that it need not amend its complaint to assert its belatedly corrected claims, the law has been clear for years that amendment is required:

Here, H-W filed this suit before the certificate of correction issued, and neither party has argued that this suit involves causes of action arising after the certificate of correction issued. ***Indeed, it appears that H-W never even sought to amend the complaint to reflect the correction of claim 9. Thus, the district court was correct not to consider the certificate of correction when determining whether H-W could assert claim 9.***

*H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1334 (Fed. Cir. 2014); *see also LG Elecs., Inc. v. Quanta Computer Inc.*, 566 F. Supp. 2d 910, 912–13 (W.D. Wis. 2008) (“any certificate of correction it received from the patent office would not be effective for the purpose of enforcement unless it filed a new lawsuit or amended its complaint”). Natera does not cite a single case permitting a party to assert corrected claims absent a properly amended complaint.<sup>1</sup> Thus, Natera should have long been on notice that it was required to amend its complaint. If Natera truly

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<sup>1</sup> Natera asserts in passing that it is permitted to assert ***uncorrected*** claims. *See* D.I. 305 at 3. This is wrong too. As the Federal Circuit held, when “a claim issues that omits a material limitation, and such omission is not evident on the face of the patent, the patentee cannot assert that claim until it has been corrected by the PTO.” *H-W Tech.*, 758 F.3d at 1335. “To hold otherwise would potentially permit patentees to assert claims that they never asked for nor rightly attained.” *Id.*; *see also Jay v. Spectrum Brands Holdings, Inc.*, No. 13CV8137-LTS-DCF, 2015 WL 2211921, at \*4 (S.D.N.Y. May 12, 2015) (The “Court finds that the undisputed material facts direct the conclusion that Claim 29 of the '316 Patent was issued with an omitted material limitation, and that the error is not evident on the face of the patent. Therefore, the uncorrected independent patent claim cannot be asserted in this litigation.”).

believed it could assert newly corrected claims without seeking to amend, it would not now be doing so.

While Natera blames Defendants for supposedly not assuming that Natera would attempt to assert corrected claims, it was Natera that should have known from the outset that its claims included uncorrected material errors. As the Federal Circuit explained, “it does not seem to us to be asking too much to expect a patentee to check a patent when it is issued in order to determine whether it contains any errors that require the issuance of a certificate of correction.” *Sw. Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1294 (Fed. Cir. 2000) (emphasis added). Natera, however, did not do this simple check. In fact, Natera’s initial infringement contentions were based on the **uncorrected** claims. It was not until nearly 18 months into the case on July 12, 2021 that Natera first served amended infringement contentions that included the proposed corrected claims.

Here, Natera waited over a year after the ’482 Patent was published before even submitting a request for a certificate of correction. This was nearly two months after Defendants first identified the defective claims in invalidity contentions. Natera’s delay in seeking to correct the claims of the ’482 patent was so extreme that at the time Natera finally served its infringement contentions with the corrected claims, the Patent Office had not even issued a certificate of correction. It thus cannot be disputed that on July 12, Natera asserted claims it had no right to assert because they had not even been allowed by the Patent Office.

Regardless, by the time Natera finally sought to correct its patent claims, this case was in its advanced stages. The parties had produced hundreds of thousands of pages of documents and countless written discovery requests. Claim construction had long since been completed. It was not until roughly two months after finally securing a certificate of correction that Natera even bothered to file a motion to amend. Natera’s conduct with regard to its corrected claims epitomizes a lack of diligence.

### **III. Natera’s Assertion Of The Corrected Claims Prior To Receiving Patent Office Approval Shows Bad Faith**

As documented above, when Natera served its final infringement contentions, it failed to provide any clear notification that it had changed the claim language in its contentions to new language for which the Patent Office had not yet even issued a certificate of correction. Apparently, Natera attempted to bury the corrected claims it was assuming the Patent Office would allow amidst hundreds of pages of claim charts in the hopes that Defendants would not notice that Natera had changed the claim language relative to its previous contentions. Natera’s attempt to silently slip the corrected claims into its final infringement contentions ***before the PTO even approved the corrected language*** is an indicator of bad faith that should not be rewarded

### **IV. Allowing Natera’s Amendment At This Late Stage Would Be Unfairly Prejudicial**

Natera’s assertion that its late amendment would not unfairly prejudice Defendants is without merit. According to Natera, “Defendants have been on notice of the Certificate of Correction since at least April 2020.” D.I. 305 at 1. Not so. Natera did not even file its request to correct the claims until June 10, 2021. Defendants, then, could not have possibly have been “on

notice” in April 2020 of a certificate of correction that Natera did not even request until June 2021. While Natera makes such efforts to blur the relevant dates to avoid an inference of prejudice, the prejudice to Defendants if Natera’s amendment were permitted is substantial.

In relevant part, the corrected claim language is as follows, with the newly added language in bold text:

1. A method for nested PCR amplification, comprising:

isolating cell-free DNA from a biological sample and ligating adaptors to the isolated cell-free DNA, wherein the adaptors each comprise a universal priming site, ***wherein (i) the adaptors each comprise a molecular barcode and/or (ii) at least one of the primers comprise a sequencing tag....***

Natera does not deny that the limitations that it omitted from its claims are material: one pertains to a molecular barcode and one pertains to a sequencing tag. The newly corrected claims create several new claim construction and invalidity issues.

For instance, the two limitations narrow all the claims of the ’482 patent and thus unfairly give Natera a greater chance of evading the prior art late in the case. Natera attempts to assert the claims for the first time on July 12, roughly 18 months into the case. When Natera first asserted these claims, there were only ***seven days*** before Defendants were required to assert final invalidity contentions. Natera’s amendment, if permitted, would thus deprive Defendants of the opportunity to do a full search for prior art and present particularized invalidity issues (including relevant claim construction issues) and otherwise take discovery specific to the corrected claims. These issues are not theoretical.

As one example, while the newly corrected claims now require the use of a “sequencing tag” on one of the “primers,” there is no antecedent basis for the “primers,” creating a serious indefiniteness issue given that there are multiple “primers” recited ***later*** in the claims. *See* Ex. F at 54, 66, 80–81, 95–96, 99. Likewise, unlike Natera’s other patents, the claims of the ’482 patent all recite that at “least 80% of the amplified DNA maps to the target loci.” *Id.* at 85. Natera will undoubtedly contend that the untimely corrected claim language plays a role in effectuating this otherwise purely functional language. In addition to creating yet additional indefiniteness issues, this also creates new enablement and written description issues. Yet, now that claim construction and fact discovery is complete, Defendants have lost the opportunity to fully pursue such issues. This is extensive prejudice, and Natera has articulated nothing to justify the imposition upon Defendants.

Instructive here is the decision from the Western District of Wisconsin in *Quanta Computer*. There, as here, the Plaintiff asserted a patent with incorrect claims. *Quanta Computer Inc.*, 566 F. Supp. at 912–13. As is the case here, the “Plaintiff says that it sought to supplement its complaint as soon as it could, but it would be charitable to call such a representation disingenuous.” *Id.* Just like Natera, the Plaintiff in *Quanta Computer* knew that “any certificate of correction it received from the patent office would not be effective for the purpose of enforcement unless it filed a new lawsuit or amended its complaint,” but nonetheless “pressed

ahead with its claims for infringement” without waiting to receive an answer from the Patent Office. *Id.*

In *Quanta Computer*, the plaintiff delayed bringing its motion to supplement. As a result, if the supplement were permitted, the parties would have been forced to do additional rounds of claim construction and defendants would have been deprived of key opportunities for summary judgment. Here too, Natera’s delay was so extreme that if its amendment were permitted, there would need to be new claim construction proceedings and Defendants would be deprived of several opportunities, including a full opportunity to prepare invalidity contentions and pursue full discovery on the new claims. The Court in *Quanta Computer* correctly concluded that “Plaintiff’s tardiness and questionable litigation strategy should not be rewarded with such a windfall” and denied the motion to supplement its complaint. *Id.*

For the reasons stated above, the Court should come to the same conclusion here.

Respectfully submitted,

/s/ Brian E. Farnan

Brian E. Farnan

cc: Counsel of Record (via E-File)